K024346

510(k) SUMMARY

MAR 0 4 2003

Submitted by:	Barnes, Richardson & Colburn 1225 Eye Street, N.W. Washington, D.C. 20005 Contact: Stephen W. Brophy Tel: (202) 457-0300
Date Prepared:	December 16, 2002
Subject Device:	Savaria Mult-lift
Predicate Device:	Savaria V-1504 Vertical Platform Lift (K960739).
Subject Product Description:	The Multilift is similar to other products in commercial distribution. These products, like the Multilift, utilize electrically driven, wall-mounted on self-standing platform units to enable individuals in wheelchairs to travel up and down between floors in a residential or public setting. See attached product information on Savaria's V-1504 Vertical Platform Lift (K960739).
Intended Use:	The Multilift is intended to mechanically transport an individual in a wheelchair directly between floors in a private residence.
Product Comparison:	The Multilift is substantially equivalent in design and function to Savaria's V-1504 Vertical Platform Lift (K960739). Also of steel construction, the V-1504 lift uses principally the same design as the Multi-lift.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

Services Industriels Savaria, Inc.
c/o Mr. Stephen W. Brophy
Barnes, Richardson & Colburn
1225 Eye Street, N.W., Suite 1150
Washington, DC 20005

Re: K024346
Trade/Device Name: Multilift: Vertical Platform Lift
Regulation Number: 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: II
Product Code: ING
Dated: February 5, 2003
Received: February 5, 2003

Dear Mr. Brophy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) : K024346

DEVICE NAME : Multilift: Vertical Platform Lift

INDICATIONS FOR USE:

The Multilift Vertical Platform Lift is intended to mechanically transport an individual in a wheelchair directly between floors in a private residence.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____
(Per 21 CFR 801.109

OR

Over-The-Counter-Use ____
(Optional Format 1)

for Mark N Melkerson

Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024346